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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,428	08/04/2006	Hiroshi Nagai	SHOB-0005 (037498-006)	9228
46188	7590	04/01/2009		
Nixon Peabody LLP 200 Page Mill Road Palo Alto, CA 94306			EXAMINER PERREIRA, MELISSA JEAN	
			ART UNIT	PAPER NUMBER
			1618	
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			04/01/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/588,428	Applicant(s) NAGAI ET AL.	
	Examiner MELISSA PERREIRA	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/18/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1,2 and 5-7 are pending in the application. Any objections and/or rejections from previous office actions that have not been reiterated in this office action are obviated.

Response to Arguments

Applicant's arguments with respect to claims 1,2 and 5-7 have been considered but are moot in view of the new ground(s) of rejection.

New Grounds of Rejection Necessitated by the Amendment

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1,2 and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zeyuan et al. (*J. Agric. Food Chem.* **1998**, 46, 3875-3878) and Xia (CN1435125; derwent Acc No 2004-023802) in view of Suzuki et al. (*J. Agric. Food Chem.* **2000**, 48, 5649-5653) and in further view of Iwasaki et al. (US 7,014,876B2).

3. Zeyuan et al. (*J. Agric. Food Chem.* **1998**, 46, 3875-3878) discloses the method of reducing and examining blood triglyceride levels in a subject via the administration of black tea extracts/functional beverage (abstract; p3876, paragraph 2, results and discussion paragraph 1; p3877, paragraphs 2 and 3). The black tea extracts/functional

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beverage were prepared by boiling black tea for 5 min and subsequently filtering (p3876, Tea for Experiment and Sample Preparation).

4. Xia (CN1435125; derwent Acc No 2004-023802) discloses a health food prepared from oolong tea which is able to reduce triglycerides (abstract).

5. The references of Zeyuan et al. and Xia do not disclose the catechins of the instant claims, such as epigallocatechin-3-O-(3-O-methyl) gallate, etc. or that the catechin is derived from the tea leaves of the instant claims, such as Benihomare, etc.

6. Suzuki et al. (*J. Agric. Food Chem.* **2000**, 48, 5649-5653) discloses the oral administration of O-methylated catechin derivatives, such as (-)-epigallocatechin-3-O-(3-O-methyl) gallate (EGCG3"Me) to mice where the EGCG3"Me is extracted from the tea leaves of Tong ting oolong tea, Benihomare cultivar (black tea), etc. The O-methylated catechin derivative EGCG3"Me and (-)-epigallocatechin-3-O-gallate (EGCG) shows inhibition of type I and IV allergy (abstract; p5649, Introduction paragraphs 1 and 2; p5651, paragraphs 2 and 3). The tea extracts of the disclosure were prepared with hot water for 30 min and are then subsequently filtered (p5650, Materials and Animals). Suzuki et al. also discloses that the daily intake of tea drinks could have potential to prevent type IV allergy (abstract).

7. Zeyuan et al. and Xia teach that both black tea and oolong tea extracts containing catechins reduce blood triglyceride levels. Therefore, at the time of the invention it would have been obvious to one skilled in the art to use/try any catechins, such as O-methylated catechin derivative EGCG3"Me of Suzuki et al. obtained from black (Benihomare cultivar) or oolong teas (Tong ting oolong) for the method of

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reducing blood triglyceride levels of Zeyuan et al. and Xia. Suzuki et al. teaches that EGCG and EGCG3"Me are analogous and therefore, it is obvious to those skilled in the art to make known substitutions on compounds that are similar in structure and function to observe the effects on the function of such compounds and to use the observations/data to further manipulate a compound to generate the desired effect. Suzuki et al. and Zeyuan et al. have identical extraction processes for the black tea extracts/functional beverage and therefore it would have been obvious to one skilled in the art that the black tea extracts/functional beverage of Zeyuan et al. will comprise O-methylated catechin derivatives.

8. The references of Zeyuan et al. and Xia also do not disclose the catechin concentration of the instant claims.

9. Iwasaki et al. (US 7,014,876B2) discloses a healthy drink containing catechins which are extracted from tea, such as Oolong tea, black tea (column 1, lines 66+; column 2, lines 32-53; column 8, lines 41+). The concentrated tea extracts are prepared by treating tea leaves with hot water (column 8, lines 41+). The catechins found in Oolong tea are used in the healthy drink in an amount from 0.092 to 0.5 g per 100 ml (column 3, lines 16-20).

10. The disclosures of Suzuki et al., Zeyuan et al. and Iwasaki et al. are drawn to the same utility, such as a extracts of black and oolong tea containing catechins via adding hot water to tea leaves and therefore at the time of the invention it would have been obvious to one skilled in the art to use the catechin extract concentration of Iwasaki et

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al. for the method of reducing blood triglyceride levels of Zeyuan et al. as the black tea extract will advantageously improve the function of the liver (Iwasaki et al.).

Furthermore, it is obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired properties such as the desired (ratios, concentrations, percentages, etc.). It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Conclusion

11. No claims are allowed at this time.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/
Examiner, Art Unit 1618